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Filing Date	June 30, 2003
First Named Inventor	Subramanian S. Venkatraman
Art Unit	1615
Examiner Name	Ghali, Isis A D
Attorney Docket Number	ARC 2869 N1

ENCLOSURES *(Check all that apply)*

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Remarks

1. Return Receipt Postcard
2. Transmittal (1 pg.)
3. Appellant's Reply Brief (14 pp.)

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

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Date	8-15-2007	Reg. No.	37,265

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: ALZA Corporation	
Inventor(s): Venkatrman et al.	Group Art Unit: 1615
Application No.: 10/611,531	Examiner: Ghali, Isis A D
Filed: June 30, 2003	
Title: TRANSDERMAL DRUG DELIVERY DEVICES COMPRISING A POLYURETHANE DRUG RESERVOIR	**Attorney Docket No.:** ARC 2869 N1

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APPELLANTS' REPLY BRIEF PURSUANT TO 37 C.F.R. § 41.41

Appellants submit this reply brief in connection with the above-identified patent application in response to the Examiner's answer mailed on July 13, 2007.

As discussed in greater detail below, the rejections based on 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) are improper and should be withdrawn.

STATUS OF THE CLAIMS

Claims 1-11, 34-53, 58 and 61 were canceled. Claims 12-33 and 54-57, and 59-60 stand finally rejected under 35 U.S.C. § 102 (a) or 103(a) in the advisory action mailed January 12, 2007 and are appealed.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether the Examiner has demonstrated that the subject matter of claims 12, 13, 15-20, 22, 33, and 54 is anticipated by U.S. patent number US4638043 ('043 Szycher);

B. Whether the Examiner has demonstrated that the subject matter of claims 12-20, 22, 33, 54, and 59-60 would have been obvious to those of ordinary skill in the art in view of the '043 Szycher patent;

C. Whether the Examiner has demonstrated that the subject matter of claims 12-33, 54-57, and 59-60 would have been obvious to those of ordinary skill in the art over the '043 Szycher patent in view of US5273757('757 Jaeger) or vise versa;

D. Whether the Examiner has demonstrated that the subject matter of claims 21, 28, 29, and 32 would have been obvious to those of ordinary skill in the art over the '043 Szycher patent in view of US5273757('757 Jaeger) and further in view of US6139866 ('866 Chono);

E. Whether the Examiner has demonstrated that the subject matter of claims 21, 28, and 30 would have been obvious to those of ordinary skill in the art over the '043 Szycher patent in view of US5273757('757 Jaeger) and further in view of US5066648 ('648 Alexander); and

F. Whether the Examiner has demonstrated that the subject matter of claim 32 would have been obvious to those of ordinary skill in the art over the '043 Szycher patent in view of US5273757('757 Jaeger) and further in view of US5599289 ('289 Castellana).

ARGUMENT

A. The Examiner's Answer fails to demonstrate that the subject matter of claims 12, 13, 15-20, 22, 33, and 54 is anticipated by U.S. patent number US4638043 ('043 Szycher)

The Examiner has failed to demonstrate that the Szycher patent teaches or suggests every limitation of the rejected claims. Specifically, the Examiner has failed to demonstrate that the Szycher patent describes the drug delivery device having a drug reservoir that has a melt-blended mixture of at least one drug and a polymer consisting of polyurethane polymer, wherein the polyurethane polymer has a process temperature of less than about 150 °C and that the polymer can be directly melt-blended with the at least one drug at less than about 150 °C without an organic solvent to result in the drug reservoir.

The Examiner seemed to consider the claims as product-by-process claims and asserted that "if the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable... ." However, (1) the present processes and the Szycher processes are not the same, (2) the present devices and the Szycher end products are not the same, and (3), the present claims are not mere product-by process claims because there are descriptions of product characteristics.

Szycher described a drug release patch with a drug releasing member containing drug in polyurethane formed from an oligomer which is cured by actinic radiation with the drug doped therein. He never described melt-mixing or melt-blending. He described only about UNCURED material as far as mixing or blending is concerned. He never mentioned that his polyurethane (which was the cured material) could be mixed or blended, regardless of temperature. He never mentioned that the ***polyurethane*** was liquid at room temperature, only that the pre-cured oligomeric material was liquid (which before curing was not suitable for a matrix layer in the device because as a liquid it would flow). The liquid PRE-CURED polymeric liquid was not yet cured and therefore was not polyurethane, but only an ingredient for making polyurethane. Curing changes the thermal and mechanical property of a material, because of cross-linking formed in the curing reaction. There is no showing that the Szycher POLYURETHANE, having been

cured, can be "melt blended with the at least one drug at less than about 150 °C without an organic solvent", as required by the rejected claims.

The Examiner asserted that the Szycher "polyurethane polymer is liquid at room temperature". However, the Examiner has confused polyurethane with its oligomer precursors. The pre-cute oligomer was liquid, the polyurethane was not liquid. If the Examiner's logic were accepted, then one would by the same logic also call a concrete mix slurry a melt-blended product, since water is liquid at room temperature. No person skilled in the art of melt-blending would call concrete mixing melt-blending, just like no body would call mixing a pre-cure oligomer composition melt-blending.

Szycher never call the precursors "polyurethane", rather he called that the "composition of liquid oligomer" (column 5, line 68). When he referred to "polyurethane", he referred to it as "polyurethane formed from oligomer" (column 3, line 22), "cured oligomer" (column 3, line 27; column, line 34), "cured polyurethane product" (column 4, line 26), "reaction product" (column 5, line 53; column 6, line 4).

Further, the Szycher material was never melt-mixed or melt-blended at all. As Appellants submitted in the Appeal Brief, to melt-mix (or melt-blend), the material has to be melted by heat to raise the temperature to render a fluid state for mixing (see also our specification page 3, lines 20-29). This is a fact well known to those skilled in the art. There are ample examples that demonstrate this fact. For example, US5536759, a reference ***incorporated by reference*** in the present application about hot melt mixing (page 3, line20-29) and cited in the Information Disclosure Statement, recited in column 1, lines 17-28, "Hot melt pressure sensitive adhesives are compositions that combine the properties of hot melt adhesives with the properties of pressure sensitive adhesives. The hot melts are solid at room temperature, melt upon application of heat, and regain their solid form on cooling."

In the conventional use of terms like "hot melt adhesive", "process temperature" and "blending" in hot melt technology it is clear that a polymer for containing the drug is melted to mix in a drug. For example, US5662923 ('923 Roreger) (which was also ***incorporated by reference*** in the present application and cited in the earlier 7/19/2005 office action) discussed "hot-melt adhesive" and "melting" (e.g., col 2, lines 62-64); "melting", "homogenizing", "mixing" (e.g., col. 3, line 61-62; col 8, lines 19-20); and

"processing temperature" (e.g., col. 5, lines 63-65). As another example, melting thermoplastic polymer and blending in the drug are also described in US6010715 (which was cited by the Examiner in the office action mailed on 1/10/2006). Thus, it is clear that to those skilled in the art, reading the present specification as a whole, melt-blending or melt-mixing in the present invention involves raising the temperature to melt the polyurethane from an un-melted state and mixing in the drug (as we do in our Example 1 in melting granules and mixing in a drug). After melt-blending and then cooling the melt-blended material to a temperature at which the product can be used, the material comes back to solid form. With the ordinary skill level of artisans, and the references incorporated by reference, there is no need for Appellants to have described commonly known details about heating to melt and cooling to solidify when such steps are clearly understood to be present in "melt-mixing" or "melt-blending" by those skilled in the art. The specification need only set forth such information as is sufficient to allow one of ordinary skill in the art to make and use the invention. How such a teaching is accomplished, either by the use of illustrative examples or by broad terminology, is of no importance since a specification which teaches how to make and use the invention in terms which correspond in scope to the claims must be taken as complying with the first paragraph of 35 U.S.C. §112 unless there is reason to doubt the objective truth of the statements relied upon therein for enabling support (In re Marzocchi, 169 USPQ 367 (CCPA) 1971).

The Examiner asserted that the burden is on the Appellants to show that the claimed product is materially different from the prior art and to show the unobvious differences. However, since the Szycher products and the claimed devices started from different materials (we started from a polyurethane polymer and melt-blended in the drug, whereas Szycher started from a liquid oligomer pre-cured composition and mixed in the drug) and used different process steps (we melt-blended and Szycher cured to cross-link), the Examiner has not even shown prima facie obviousness or similarity of the products and processes of the presently claimed invention over Szycher, not to mention anticipation of the claims.

The Szycher ***polyurethane*** is a cured product and is materially different from the polyurethane of the presently claimed products. The Szycher oligomer liquid

composition (not polyurethane) was mixed with a drug at room temperature. There was no melting, since melting requires heating from a non-liquid state to a liquid state. Of course, there was no subsequent cooling either. Thus, There was no melt-mixing (or melt-blending). The oligomer composition was cured to a solid by radiation. There is no indication that the Szycher cured oligomer, i.e., his polyurethane, can be processed in melt-mixing at less than about 150 °C to include a drug without an organic solvent. Thus, in '043 Szycher, there was no polyurethane that can be processed to include a drug at less than about 150 °C without an organic solvent.

Therefore, the claimed devices, accordingly, would not have been anticipated by '043 Szycher, and the Examiner has failed to establish otherwise.

B. The Examiner's Answer fails to demonstrate that the subject matter of claims 12-20, 22, 33, 54, and 59-60 would have been obvious to those of ordinary skill in the art in view of the '043 Szycher patent

As discussed above, the Examiner has failed to demonstrate that the Szycher patent teaches every limitation of the rejected claims. Likewise, the Examiner has failed to demonstrate that the Szycher patent renders obvious the rejected claims.

The Examiner asserted the Szycher "polyurethane polymer is liquid at room temperature to facilitate admixture of drug to form a homogenous blend". Again, the Examiner was confused about what Szycher considered to be polyurethane. As Appellants submitted above, what was liquid at room temperature to facilitate admixture was the Szycher oligomer composition, NOT the polyurethane, which according to Szycher was cured. As can be seen clearly in the figures of '043 Szycher, the Szycher polyurethane was solid, not liquid at room temperature.

The Examiner admitted that Szycher '043 did not explicitly teach that the process temperature and the modulus of the polyurethane polymer. Nevertheless, the Examiner still asserted that "the process temperature and the modulus of the polyurethane disclosed by US '043 are expected to be the same as instantly claimed because the reference teaches the same polymer formed from the same polymer reaction that is liquid at room temperature...." If the Examiner is arguing that the same product as the claims product was formed by Szycher because the same polymer reaction was used by Szycher as the

present invention, the Examiner has not demonstrated that the polymer reactions were the same.

First, as Appellants submitted earlier, Szycher never melt-blended anything since there was ***never any melting*** step in his reaction. One cannot melt-blend without melting. There was never any solidifying by cooling either. If you start with a liquid and solidify it with a curing process, that process is not melt-blending. Thus, the process was different, and therefore the product would be different.

Second, the ***claimed characteristics*** of the product of the present invention are different from the Szycher product. In the claimed product, the drug reservoir has a polyurethane polymer having a process temperature of less than about 150 °C, wherein the polymer can be directly melt-blended with the at least one drug at less than about 150 °C without an organic solvent. Thus, the polyurethane has such specific characteristics that it is melt-blendable at less than about 150 °C to include a drug without an organic solvent. There is no such polyurethane in the Szycher product.

Further on the characteristics of the polyurethane, claim 57 specifically points out that the "polyurethane polymer can be directly melt-blended starting from granules with the at least one drug... at less than about 150 °C without an organic solvent... ." Nowhere in the Szycher patent was it ever mentioned, suggested, or hinted that Szycher's polyurethane can be directly melt-blended starting from **GRANULES** with a drug at less than about 150 °C without an organic solvent. The Szycher oligmer composition was liquid at room temperature. There is no indication that the cured Szycher polyurethane can be directly melt-blended starting from granules with a drug at less than about 150 °C without an organic solvent.

Also, in the Examiner's answer, the Examiner admitted that Szycher did not mention phase separation in regard to claim 54, but still asserted that "claim 54 is obvious over Szycher." Appellants are puzzled as to the logics of that assertion. Knowing that melt-blending sometimes can result in phase separation, Appellants are at a loss as to how the complete absence of any mention of a limitation in cited references on phase separation can lead to obviousness.

Therefore, the claimed devices, accordingly, would not have been obvious over Szycher '043, and the Examiner has failed to establish otherwise.

C. The Examiner's Answer fails to demonstrate that the subject matter of claims 12-33, 54-57, and 59-60 would have been obvious to those of ordinary skill in the art over the '043 Szycher patent in view of US5273757('757 Jaeger) or vise versa

As discussed above, the Examiner has failed to demonstrate that the Szycher patent renders obvious the rejected claims. Likewise, the Examiner has failed to demonstrate that the Szycher patent in view of US5273757('757 Jaeger) or vise versa renders obvious every limitation of the rejected claims.

The Examiner asserted and that it would be obvious for one skilled in the art to follow the teaching of '757 Jaeger about hot melt adhesive layer comprising 10-100% polyurethane adhesive, 10-80% plasticizer such as fatty acid esters, and drug such as fentanyl using temperature between 40°C to 80°C without solvent.

Here, the Examiner has confused the adhesive (mixture) with the polyurethane (which is in the mixture).

The Szycher patent has been discussed above. Jaeger does not cure the shortcomings of Szycher. It is noted that the polyurethane in the mixture of Jaeger constituted no more than half of the hot melt adhesive ('757 Jaeger col. 6, lines 12-21). There surely were a lot of other materials in the Jaeger adhesive: hydrogenated alcohol, hydrocarbon resin, esters of vegetable fatty acids, antiagers, and fillers, up to 50% of the adhesive! Esters of vegetable fatty acids, hydrogenated alcohol, and hydrocarbon resin have plasticizer functions. As Appellants submitted in the Appeal Brief (with cited support), it is known that plasticizers are able to decrease the glass transition temperature and the melt viscosity of a hot melt polymer: "With the addition of a plasticizer, a hot melt process can be conducted with lower temperature and with less torque."

It is noted that in the claimed devices, the polyurethane is characterized to possess certain properties: "having a process temperature of less than about 150 °C, wherein the polymer can be directly melt-blended with the at least one drug at less than about 150 °C without an organic solvent to result in the drug reservoir." With a large amount of such non-polyurethane plasticizers in the Jaeger adhesive, the thermal property of the Jaeger ***adhesive mixture*** would be very different ***from that of the polyurethane*** ingredient. Jaeger did not tell us what the melt-blending processing temperature of the ***polyurethane***

in the adhesive was. Jaeger only stated that the pressure sensitive adhesive (i.e., the ***adhesive mixture*** with drug active substance as well as other exipients) had a processing temperature of 40 – 80 °C (see e.g., column 2 lines 50-51). Jaeger did not say that the polyurethane of the adhesive had a processing temperature of 40 – 80 °C. But in our claims, it is required that the ***polyurethane*** in the melt-blended material has this property.

The Examiner asserted that there is reasonable expectation from the combination of Szycher with Jaeger to make a matrix of melt blend of polyurethane, fentanyl, and fatty acid esters that processed at 40 – 80 °C without solvent. However, how is that possible when neither Szycher nor Jaeger disclosed polyurethane that has a processing temperature of at 40 – 80 °C without solvent? Further, how can Jaeger modify Szycher and vise versa to arrive at the present claims? Is the Examiner suggesting adding 50% or more of excipients to the pre-cured oligomer composition, or to the cured material? If the >50% of excipients were added to the pre-cure oligomer composition, the curing may never proceed properly. If the >50% of excipients were added to the material after curing, the ingredients may not mix at all. Even within the Jaeger process, the material in the adhesive was nonuniform. Who knows what worse situation may arise if one were to mix >50% of excipients into a cured material. There is no expectation of success.

Therefore, the claimed devices, accordingly, would not have been obvious over Szycher '043 in view of '757 Jaeger, and the Examiner has failed to establish otherwise.

D. The Examiner's Answer fails to demonstrate that the subject matter of claims 21, 28, 29, and 32 would have been obvious to those of ordinary skill in the art over the '043 Szycher patent in view of '757 Jaeger and further in view of US6139866 ('866 Chono)

As discussed above, the Examiner has failed to demonstrate that the Szycher patent in view of the '757 Jaeger patent renders obvious the rejected claims. Likewise, the Examiner has failed to demonstrate that the Szycher patent in view of the '757 Jaeger patent and further in view of '866 Chono renders obvious the rejected claims.

The Examiner asserted and that it would be obvious to combine the use of permeation enhancer such as glycerol such as glycerol monolaurate as disclosed by Chono with the disclosures of '043 Szycher and '757 jaeger to arrive at the present invention.

However, the adhesive/drug mixing was apparently done ***with solvent*** (column 5, lines 24-35 mentioning solvent method; column 6, lines 16-20 mentioning solvent ethanol). It is irrelevant to solventless melt-blending. The references have to be taken as a whole. Absent appropriate teaching, the Examiner cannot pick and choose from prior art references to arrive at the presently claimed invention. Further, Chono did not mention polyurethane as a drug layer material, much less anything about melt-blending with polyurethane. Chono mentioned polyurethane only for the backing layer, which further shows that Chono was not unaware of polyurethane, he just did not consider polyurethane as a suitable drug reservoir material.

The Examiner also relied on Chono for his teaching on acrylate adhesive as skin contact adhesive. It is noted that in Chono, however, the acrylate was mentioned for the drug reservoir, not as an in-line adhesive adjacent to a polyurethane drug reservoir, in which case the drug has to pass from the polyurethane through the acrylate adhesive to the skin. Yet the Examiner asserted that there is "reasonable expectation of having a transdermal device comprising layer comprising polyurethane, fenatnyl and glycerol monolaurate, and further add acrylate adhesive skin contact layer... ." It is a well known fact that different layers of different materials in contact would greatly affect drug permeation due to the partition coefficients, solubilities of the drug and excipients (such as permeation enhancers) in the respective layers, etc., which depend on the specific layer materials and the specific drug. A person cannot blindly substitute one drug, one layer, or one enhancer for another and expect it to work.

Therefore, the claimed devices, accordingly, would not have been obvious over Szycher '043 in view of '757 Jaeger and further in view of '866 Chono, and the Examiner has failed to establish otherwise.

E. The Examiner's Answer fails to demonstrate that the subject matter of claims 21, 28, and 30 would have been obvious to those of ordinary skill in the art over the '043 Szycher patent in view of US5273757('757 Jaeger) and further in view of US5066648 ('648 Alexander)

As discussed above, the Examiner has failed to demonstrate that the Szycher patent in view of the '757 Jaeger patent renders obvious the rejected claims. Likewise,

the Examiner has failed to demonstrate that the Szycher patent in view of the '757 Jaeger patent and further in view of '648 Alexander renders obvious the rejected claims.

The Examiner asserted that Alexander taught pyroglutamic acid esters as permeation enhancers for analgesics and sedatives, and therefore one skilled in the art will be led to deliver fentanyl with the enhancers in our claimed invention. The Examiner further simply asserted that enhancer "[p]yroglutamic acid esters will enhance the delivery of any drug and its amount depends on the solubility, hydrophilicity and lipophilicity of the drug that controls the transport of the drug across the stratum corneum." This blanket statement oversimplifies matters to the extreme. If what the Examiner asserted were true, there would never be any need for further research and people can simply throw a few known enhancers together with some drug in some reservoir material and expect it to deliver transdermally at a desired rate, and there would have been hundreds of commercial trandermal patches for all kinds of drugs and reseveroirs. This picture, of course, is not true. Workable transdermal patches are very rare. Experience has told us that one enhancer may work for one drug and not for another even under otherwise similar circumstances. That is why there are so few trandermal drug delivery patches in the market. Alexander does ***not mention fentanyl***, and does ***not mention polyurethane*** as the drug layer carrier polymer. Furthermore, Alexander has ***nothing to do with melt-blending***. Even if it were assumed that one would combine the references there is no expectation of success that fentanyl can be effectively delivered in a polyurethane melt-blended mix.

F. The Examiner's Answer fails to demonstrate that the subject matter of claim 32 would have been obvious to those of ordinary skill in the art over the '043 Szycher patent in view of '757 Jaeger and further in view of US5599289 ('289 Castellana)

As discussed above, the Examiner has failed to demonstrate that the Szycher patent in view of the '757 Jaeger patent renders obvious the rejected claims. Likewise, the Examiner has failed to demonstrate that the Szycher patent in view of the '757 Jaeger patent and further in view of '289 Castellana renders obvious the rejected claim 32.

The Examiner asserted that because Castellana taught that acrylate adhesive layer is preferred because it is non-irritating and therefore the combination of Szycher, Jaeger and Castellana would render obvious claim 32. However, the Castellana patent is not even relevant to transdermal drug delivery, but is about a wound dressing. Castellana did not mention fentanyl, did not mention polyurethane, had nothing to do with melt-mixing and was absolutely unrelated to in-line adhesive that is adjacent to a drug in polyurethane reservoir. Further, in Castellana's wound dressing the antibiotic can penetrate THROUGH THE WOUND and will no longer be needed once the wound heals. This is entirely different from transdermal delivery that requires the drug to penetrate the INTACT skin at a therapeutic rate over an extended period of time. As discussed above, in the claimed invention, the drug has to pass from the polyurethane reservoir through the acrylate in-line adhesive to the skin and such drug penetration depends on partition coefficients, solubilities, relative hydrophobicities of the layers and the drug, etc. Of course, Castellana had no teaching or relevance to these considerations. A person skilled in the art will not glean anything from Castellana to combine with Sycher and Jaeger and there would be no expectation of success even if one were to try.

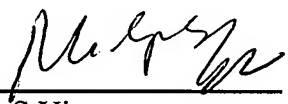
Therefore, the claimed devices, accordingly, would not have been obvious over Szycher '043 in view of '757 Jaeger and '289 Castellana, and the Examiner has failed to establish otherwise.

Conclusion

For the foregoing reasons, and those set forth in the appeal brief, Appellants request that this patent application be remanded to the examiner with an instruction to both withdraw the outstanding rejections, and to allow the appealed claims. For any of the Examiner's assertions in the Examiner's answer that Appellants have not directly traversed, Appellants do not acquiesce on such assertions and the Appeal Board is respectfully requested to consider the Appeal Brief for arguments against such assertions.

The Commissioner is hereby authorized to charge any additional fees associated with this paper or during the pendency of this application, or credit any overpayment, to Deposit Account No. 10-0750.

Respectfully submitted,



Date: August 15, 2007

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